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PTO/SB/21 (08-03) Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. Application Number 10/088,629 Filing Date TRANSMITTAL 03/19/2002 **FORM** First Named Inventor Heithoff Art Unit 1614 (to be used for all correspondence after initial filing) **Examiner Name** Phyllis G. Spivack Attorney Docket Number AL01071K Total Number of Pages in This Submission **ENCLOSURES** (Check all that apply) After Allowance communication M Fee Transmittal Form Drawing(s) to Group Appeal Communication to Board Licensing-related Papers of Appeals and Interferences Fee Attached Appeal Communication to Group Petition (Appeal Notice, Brief, Reply Brief) Amendment/Reply Petition to Convert to a Proprietary Information After Final Provisional Application Power of Attorney, Revocation Status Letter Affidavits/declaration(s) Change of Correspondence Address Other Enclosure(s) (please Terminal Disclaimer Identify below): **Extension of Time Request** Request for Refund Express Abandonment Request Reference (9 documents); Return Post Card CD, Number of CD(s) Information Disclosure Statement Remarks Certified Copy of Priority Document(s) Response to Missing Parts/ Incomplete Application Response to Missing Parts under 37 CFR 1.52 or 1.53 SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT Firm Individual name THOMAS D. HOFFMAN, Reg. No. 28,221 Signature Date March 3, 2004 CERTIFICATE OF TRANSMISSION/MAILING I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with

sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.

Typed or printed name			
	THOMAS D. HOFFMAN, Reg. No. 28,221		
Signature	Thomas D Hoffma	Date	March 3, 2004

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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FEE	ETR	AN	SMIT	TAL
•	for	FY	2004	

Effective 10/01/2003. Patent fees are subject to annual revision.

Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT

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Complete if Known				
Application Number	10/088,629			
Filing Date	03/19/2002			
First Named Inventor	Heithoff			
Examiner Name	Phyllis G. Spivack			
Art Unit	1614			
Attorney Docket No.	AL01071K			

METHOD OF PAYMENT (check all that apply)	FEE CALCULATION (continued)					
Check Credit card Money Other None 3. ADDITIONAL FEES						
Deposit Account:	Large Entity   Small Entity					
	Fee Fee Fee Fee Fee Description					
Deposit Account 19-0365		ee Paid				
Number Deposit	1051 130 2051 65 Surcharge - late filling fee or oath					
Account Schering-Plough Corporation	1052 50 2052 25 Surcharge - late provisional filing fee or cover sheet					
Name The Director is authorized to: (check all that apply)	1053 130 1053 130 Non-English specification					
Charge fee(s) indicated below Credit any overpayments	1812 2,520 1812 2,520 For filing a request for ex parte reexamination					
Charge any additional fee(s) or any underpayment of fee(s)	1804 920" 1804 920" Requesting publication of SIR prior to Examiner action					
Charge fee(s) indicated below, except for the filing fee	1805 1,840* 1805 1,840* Requesting publication of SIR after Examiner action					
to the above-identified deposit account.	1251 110 2251 55 Extension for reply within first month					
FEE CALCULATION		20.00				
1. BASIC FILING FEE Large Entity Small Entity	1253 950 2253 475 Extension for reply within third month					
Fee Fee Fee Fee Description Fee Paid	1254 1,480 2254 740 Extension for reply within fourth month					
Code (\$) Code (\$)	1255 2,010 2255 1,005 Extension for reply within fifth month					
1001 770 2001 385 Utility filing fee 1002 340 2002 170 Design filing fee	1401 330 2401 165 Notice of Appeal					
	1402 330 2402 165 Filing a brief in support of an appeal					
1003 530 2003 265 Plant filing fee 1004 770 2004 385 Reissue filing fee	1403 290 2403 145 Request for oral hearing	———				
1005 160 2005 80 Provisional filing fee	1451 1.510 1451 1.510 Petition to institute a public use proceeding					
	1452 110 2452 55 Petition to revive - unavoidable					
SUBTOTAL (1) (\$) 0	1453 1,330 2453 665 Petition to revive - unintentional					
2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE	1501 1,330 2501 665 Utility issue fee (or reissue)					
Fee from Ext <u>ra Claims below Fee Paid</u>						
Total Claims = X =	1503 640 2503 320 Plant issue fee					
Independent Claims - 3** = X = =	1460 130 1460 130 Petitions to the Commissioner					
Multiple Dependent	1807 50 1807 50 Processing fee under 37 CFR 1.17(g)					
Large Entity   Small Entity	3	80.00				
Fee Fee Fee Fee Description Code (\$) Code (\$)	8021 40 8021 40 Recording each patent assignment per					
1202 18 2202 9 Claims in excess of 20	property (times number of properties) 1809 770 2809 385 Filing a submission after final rejection					
1201 86 2201 43 Independent claims in excess of 3	(37 ČFR 1.129(a))					
1203 290 2203 145 Multiple dependent claim, if not paid	1810 770 2810 385 For each additional invention to be					
1204 86 2204 43 ** Reissue independent claims over original patent	examined (37 CFR 1.129(b))  1801 770 2801 385 Request for Continued Examination (RCE)					
1205 18 2205 9 ** Reissue claims in excess of 20 and over original patent	1802 900 1802 900 Request for expedited examination of a design application					
Other for Jone (A)						
SUBTOTAL (2) (\$) 0 *Reduced by Basic Filing Fee Paid SUBTOTAL (3) (\$) 600.00						
SUBMITTED BY	(Complete (if applicable))					

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Registration No.

(Attorney/Agent)

28,221

Telephone

Date

908-298-5037

March 3, 2004

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Name (Print/Type)

Signature

THOMAS D. HOFFMAN

9



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): KIM A. HEITHOFF

Group Art Unit: 1614

Serial No.: 10/088,629 Examiner: Phyllis G. Spivak

Filed:

03/19/2002

Attorney Docket No.: AL01071K

For:

TREATING ALLERGIC AND

INFLAMMATORY CONDITIONS

## INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450 Schering-Plough Corporation Patent Department K-6-1 1990 Kenilworth, NJ 07033

Sir:

## Response

This is in response to the Official Action dated Oct.3, 2003 rejecting claims 9-55 as being unpatentable under 35USC§103(a).

Applicant respectfully requests reconsideration and withdrawal of the grounds of rejection.

Applicant encloses the following: (1) an Information Disclosure Statement and Form PTO - 1449 with copies of nine (9) references; (2) a Response Transmittal Form; (3) a Petition and Fee for a Two Month Extension of Time to Respond, (4) a Fee Transmittal Form (in duplicate), and (5) a Return Post Card.

## Remarks

Claims 9-55 stand rejected under 35USC§103(a) as being unpatentable over Katz in view of Handley et al.

Applicant disagrees and requests reconsideration and withdrawal of the grounds of rejection.

Katz teaches administration of loratadine to students with seasonal allergic rhinitis who may experience decreased academic performance and productivity. Katz also discloses in the paragraph entitled "Goods of Pharmacological Intervention in Students with Allergic Rhinitis" on the top of page 46 that "young adults". are a different class of patient than the "general population", i.e., adults and are close to the "elderly". (emphasis added)

In the "Conclusion" on page 98. Katz provides the following teaching regarding "young" adults:

> "clinicians should be aware that students are an active group that may benefit from treatment with the nonsedating second-generation antihistamines. Clinicians should have the ability to identify treatments that do not limit academic or physical performance in school-age patients" (emphasis added)

Applicant's claimed inventions is directed to methods of substantially returning workplace productivity of a person suffering from an allergic and/or inflammatory condition of

00000112 190365 10088629 03/10/2004 HLE333

Serial No. <u>10/088,629</u> March 3, 2004 Page 2 of 2

the skin or passages to the person's baseline workplace productivity by administering an initial amount of desloratadine to said person effective for such returning.

Applicant asserts that (1) Katz does not touch his claimed invention and that (2) Handley et al cures none of the deficiencies of Katz.

Handley et al teach using desloratadine to treat allergic asthma and dermatitis in humans while avoiding the liability of adverse side effects associated with the administration of non-sedating antihistamines. Such side effects are reported to included cardiac arythmia and tumor promotion. Applicant asserts that "such reported side effects" would unlikely be present in students or young adults so there appears to be no incentive to combine the teachings of Handley with Katz, without reference to applicant's own claimed invention.

Reconsideration and withdrawal of this ground of rejection is urged.

If applicant's attorney can be of any assistance in advancing prosecution, please contact him.

Respectfully submitted,

Thomas D. Hoffman

Attorney of Record for Applicant

Reg. No. 28,221

Tel: 908-298-5037

Sheet 1 of 1 MADE TO M PTO-1449 U.S. DEPARTMENT OF COMMERCE APPLICATION NO.: ATTY, DOCKET NO .: PATENT AND TRADEMARK OFFICE AL01071K 10/088,629 ANFORMATION DISCLOSURE STATEMENT APPLICANT: Heithoff BY APPLICANT FILING DATE: GROUP: (Use several sheets if necessary) 03/19/2002 1614 U.S. PATENT DOCUMENTS DATE NAME CLASS SUB-FILING DATE IF \*EXAMINER DOCUMENT NUMBER CLASS APPROPRIATE INITIAL 514 AA 6,054,463 04/25/2000 Handley et al 290 514 290 AB 5,900,421 05/04/1999 Handley et al. 290 514 AC 5,595,997 01/21/1997 Aberg et at. AD 4,659,716 04/21/1987 Villani et al. 514 290 FOREIGN PATENT DOCUMENTS COUNTRY CLASS SUB-TRANSLATION DOCUMENT DATE **CLASS** NUMBER YES NO WO 98 48803 WIPO ΑE 11/05/98 Х AF WO 98 34614 A 08/13/98 | WIPO WIPO AG WO 98 06394 A 02/19/98 OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) Genovese: 'loratadine and desethoxycarbonyl loratadine...' CLINICAL AND EXPERIMENTAL ALLERGY, vol. 27, no. 5, 1997, pages 559 - 567 ΑI Molet, S. et al: 'Inhibitory activity of loratadine and descarboxyethoxyloratadine on histamineinduced activation of endothelial cells' CLIN EXP. ALLERGY (1997), 27 (10), 1167-1174 **EXAMINER** DATE CONSIDERED

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.